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Subject: Environmental Defense comments on Diallyldimethylammonium Chloride (CAS# 7398-69-8)

(Submitted via Internet 9/10/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Bobf@regnet.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Diallyldimethylammonium Chloride (CAS# 7398-69-8).

The Diallyldimethylammonium Chloride Panel, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposed testing to address SIDS elements required for diallyldimethylammonium chloride (DADMAC).

DADMAC is said by the sponsor to be produced and used "almost" exclusively in closed systems in three separate manufacturing plants for use in the synthesis of water-soluble polymers used as coagulants in water treatment, paper-making and textile printing. Other uses, their significance and possible sources of human or environmental exposure are not mentioned. (According to the test plan, less than 25% of the material produced is transported in interstate commerce. This statement has little meaning if we are not informed of the total production volume of DADMAC. That is, if this is a very high production volume chemical, 25% could be a very significant amount. However, this deficiency has little practical significance in relation to the HPV Challenge, as the sponsor of this submission does not propose that DADMAC be considered a closed-system intermediate.)

Data, actual or modeled, are described to address most required SIDS elements for this chemical, and additional studies are proposed to address ecotoxicity. However, those data addressing its chemical and physical properties and environmental fate are described only in the robust summaries and are not provided in the test plan. They need to be summarized in the test plan.

Most of the studies described for DADMAC are somewhat dated and were not conducted under GLP, but our review of the robust summaries indicates they are adequate to address most of the required SIDS elements. Results of these studies indicate this chemical has low environmental and mammalian toxicity for the endpoints tested, and that it is not mutagenic. Further, if released into the environment, it should degrade relatively rapidly. As mentioned above, data are available to address most of the SIDS elements required under the HPV initiative. However, in the course of our review of this submission we did note the following concerns.

1. The studies of reproductive/developmental toxicity used the homopolymer containing only low concentrations of the DADMAC monomer. We do not think these low concentrations of monomer were sufficient to determine the

reproductive/developmental toxicity of DADMAC; therefore, we request that new studies be conducted using appropriate doses of the monomer.
2. The test plan gives the LC50 to blue gill fish as 56 mg/l. However, the description of this study in the robust summaries indicates no blue gill fish died when exposed to 56 mg/l. The only indication of any toxicity to fish is a misplaced sentence in a portion of the robust summaries describing toxicity to soil microbes, section 4.4, which states that fish exposed to 56 mg/l swam more slowly than other fish. These discrepancies need to be resolved.
3. The description of the absorption, distribution, metabolism and excretion study with rats is inconsistent in that it states that three animals were treated at each time point and then goes on to indicate that one animal was treated at each of three time points. Which is correct?

In summary, this submission should be revised to eliminate the above inconsistencies. More importantly, unless EPA decides that the studies with the homopolymer containing low levels of DADMAC are sufficient to address the requirement for studies of reproductive and developmental toxicity on DADMAC, these studies need to be performed on the monomer itself. Otherwise, this submission appears to be an acceptable response to the HPV Chemical Challenge.

Thank you for this opportunity to comment.

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